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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR FILING DATE APPLICATION NO. 07334/004002 SHYJAN 08/862,442 05/23/97 **EXAMINER** HM22/0731 CANELLA,K J PETER FASSE PAPER NUMBER ART UNIT FISH & RICHARDSON 27 225 FRANKLIN STREET 1642 BOSTON MA 02110-2804 DATE MAILED: 07/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Application No.

Applicant(s)

08/862,442

Shyjan

Office Action Summary

Examiner

Karen Canella

Group Art Unit 1642



Responsive to communication(s) filed on	
☐ This action is FINAL.	aution as to the marits is closed
☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay#835 C.D. 11; 453 O.G. 213.	
A shortened statutory period for response to this action is set to expire 3 months month longer, from the mailing date of this communication. Failure to respond within the period application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained 37 CFR 1.136(a).	th(s), or thirty days, whichever is for response will cause the ed under the provisions of
Disposition of Claim	is/are pending in the applicat
Disposition of Claim ★ Claim(s) 29, 31-38, 43, 45-50, and 54	is/are withdrawn from consideration
Of the above, claim(s)	is/are withdrawn nom consideration
	IS/are allowed.
Mr. Olaim (a) 20, 24, 28, 43, 45,50, and 54	
☐ Claim(s) are subj	ect to restriction or election requirement.
See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. ☐ The drawing(s) filed on)-(d). have been CT Rule 17.2(a)).
Attachment(s) ☐ Notice of References Cited, PTO-892 ☑ Information Disclosure Statement(s), PTO-1449, Paper No(s)	
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

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DETAILED ACTION

Continued Prosecution Application

- 1. The request filed on 5/26/00, in Paper No. 24, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/862,442 is acceptable and a CPA has been established. An action on the CPA follows.
- 2. Claims 29, 31-38, 43, 45-56 are pending and examined on the merits.

Claim Objections

3. Claim 35 is objected to because of the following informalities: Claim 35 recites "amino acid sequences" in reference to a single DNA clone. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 5. Claims 29, 31-38, 43, 45-50 and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 29, 31-38, 43, 45-50 and 54 are rejected under 35 USC 112, first paragraph as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials.

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Applicant's referral to the deposit of clone FOMY030 on pages 44 and 129 of the specification is insufficient assurance that all of the conditions of 37 CRF sections 1.801 through 1.809 have been met. If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon grant of a patent on this application and that the deposit will be replaced if viable samples cannot be despensed by the depositiry is required. This requirement is neccessary when a deposit is made under the provision of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State.

- 6. Claims 29-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 29, 37 and 38 are drawn to a polypeptides comprising amino acids 1-844 and 850-1497 of SEQ ID NO:7. The specification only discloses SEQ ID NO:3, 7 and 9. Polypeptides comprising amino acids 1-844 or 850-1497 can be interpreted to read on a broad genus of polypeptides having only residues 1-844 or 850-1497 in common with SEQ ID NO:7. One skilled in the relevant art would not be convinced that the applicant possessed at the time the application was filed, more than polypeptides consisting of residues 1-844 and residues 850-1497 of SEQ ID NO:7.
- 7. Claims 29-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 29, 37 and 38 are drawn to a polypeptides comprising amino acids 1-844 and 850-1497 of SEQ ID NO:7. The specification only discloses SEQ ID NO:3, 7 and 9.

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Polypeptides comprising amino acids 1-844 or 850-1497 can be interpreted to read on a broad genus of polypeptides having only residues 1-844 or 850-1497 in common with SEQ ID NO:7. The specification does not describe the sequence or use of other isolated polypeptides beyond SEQ ID NO:3, 7 and 9. Without a description of function in the instant claims, one of skill in the art would not know how to use the polypeptides of claims 29, 37 or 38.

- 8. Claims 43, 45-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 43-56 are broadly drawn to isolated polypeptides encoded by a nucleic acid molecules which hybridize under stringent conditions to the nucleic acid molecule of SEQ ID NO: 2,6, 8, the cDNA of NRRL Deposit No: B21426, ATTC Accession No:97880 or 97881. The specification discloses the amino acid sequences SEQ ID NO:3, 7 and 9. Nucleic acid molecules which hybridize under stringent conditions to the nucleic acid molecule of SEQ ID NO: 2, 6 or 8 can include a plethora of single base pairing mismatches, resulting in alterations of the transcribed amino acid sequence. The specification does not describe other isolated polypeptides beyond SEQ ID NO:3, 7 and 9. One of skill in the relevant art would not be convinced that the inventor's had in their possession, more than SEQ ID NO:3, 7 and 9 at the time the application was filed.
- 9. Claims 43, 45-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 43-56 are broadly drawn to isolated polypeptides encoded by a nucleic acid molecules which hybridize under stringent conditions to the nucleic acid molecule of SEQ ID NO: 2,6, 8, the cDNA of NRRL Deposit No: B21426, ATTC Accession No:97880 or 97881. The specification discloses the amino acid sequences SEQ ID NO:3, 7 and 9. Nucleic acid molecules which hybridize under stringent conditions to the nucleic acid molecule of SEQ ID NO:

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2, 6 or 8 can include a plethora of single base pairing mismatches, resulting in alterations of the transcribed amino acid sequence. The specification does not describe the sequence or use of other isolated polypeptides beyond SEQ ID NO:3, 7 and 9. Without a description of function in the instant claims, one of skill in the art would not know how to use the polypeptides of claims 43-56.

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10. Claims 29, 31-38, 43, 45-56 are free of the art.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D. Patent Examiner, Group 1642

July 26, 2000

IANCY A. JOHNSON, PH.D